

K081410

Section 5

JUN - 4 2009

510(k) Summary
Rex Medical Option Vena Cava Filter System

Submitter: Rex Medical
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Date Prepared: June 2, 2009

Trade Name: Option* Vena Cava Filter System

Classification Name: Cardiovascular Filter

Classification Number: 21 CFR 870.3375

Product Code: DTK

Predicate Devices: Boston Scientific Corporation's SS Greenfield Vena Cava Filter – K964284, determined substantially equivalent on January 6, 1997 (also K955396, K951508)

Cordis Optease Vena Cava Filter – K023116 determined substantially equivalent on October 18, 2002.

Cordis Trapease Vena Cava Filter - K000062 determined substantially equivalent on July 7, 2000

Bard Recovery Vena Cava Filter – K022236 determined substantially equivalent on November 27, 2002

Recovery G2 Filter - K073090 determined substantially equivalent on January 15, 2008

Gunther-Tulip Vena Cava Filter Set – K032426 determined substantially equivalent on October 31, 2003.

Device Description: The Rex Medical Option Vena Cava Filter System consists of a self-centering vena cava filter made from nickel-titanium

alloy (Nitinol). The filter consists of shape memory nitinol struts emanating from a central location and designed for clot capture. Retention anchors are located at the caudal portion of the filter. These anchors are intended for filter fixation into the cava wall. The Option Filter is intended for use in cava diameters up to 30mm.

The delivery system consists of the filter preloaded in a filter cartridge, a 5French catheter sheath introducer, an open-ended angiographic vessel dilator which may be used for infusion of contrast solution during placement and a pusher with deployment marker.

Intended Use:

The Option* Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism when anticoagulant therapy has failed or is contraindicated

The filter may be retrieved according to the instructions supplied in section entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

Functional Testing:

Mechanical bench testing, *in vivo* animal testing and clinical testing were performed. In some instances, legally marketed vena cava filters were tested as control devices for the purpose of comparison with the Option Vena Cava Filter System.

In addition, testing was also performed in accordance with the following Special Controls for Cardiovascular Intravascular Filters (21 CFR 870.3375):

- International Standards Organization's ISO-10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,

- FDA's Updated 510(k) Sterility Review Guidance (K90-1); Final Guidance for Industry and FDA, August 30, 2002, and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions

**Summary of Substantial
Equivalence:**

The design, material, components, fundamental technology and intended use of the Rex Medical Option Vena Cava Filter System for the permanent indication with the option for removal are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon not only descriptive characteristics of the various devices but also upon the safety and performance testing completed. Based upon this information, the Rex Option Vena Cava Filter System has been shown to be substantially equivalent to the predicate devices for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2009

Rex Medical
c/o Mr. Leo L. Basta
Boston Biomedical Associates, LLC
386 West Main Street, Suite #7
Northboro, MA 01532

Re: K081410
Trade/Device Name: Option Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II (Two)
Product Code: DTK
Dated: April 6, 2009
Received: April 7, 2009

Dear Mr. Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/cdrh/comp/> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K081410
~~Not Assigned~~

Device Name: Option* Vena Cava Filter System

Indications for Use:

The Option* Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
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Prescription Use: X AND/OR Over-The Counter Use:
(Per 21 CFR 801 Subpart D)..... (Per 21 CFR 801 SubpartC)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE
ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana P. Williams
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081410